REMARKS/ARGUMENTS

Claims 83-105 were pending in this application prior to this communication. Claims 1-82 have been previously canceled. Claims 83, 88-90, 92-94, 99 and 105 have been amended herein. Claims 84-87 and 97 have been cancelled by herein. Claims 83, 88-96 and 98-105 are currently pending.

By the amendments, Applicants do not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

1. Claim Objections

a. Claim 93

Claim 93 is objected to because of the following informalities: --then—should be replaced with –than--. Applicants have corrected the informality in claim 93.

b. Claim 98

Claim 98 is objected to because of the following informalities: "second" is repeated twice in line 4. Applicants have corrected the informality in claim 98.

2. 35 U.S.C. §102 Rejections

a. Claims 83-92 are rejected under 35 USC §102(b) as being allegedly anticipated by Von Oepen (US 6,017,365).

Applicants have amended claim 83 to now incorporate the subject matter of previously dependent claims 84, 86, 88, 89, and 92, which have been either cancelled or amended to further develop certain aspects of amended independent claim 83. As a result, among other aspects, claim 83 now addresses: only a stent with a segment along its first end portion that has a different lattice structure than another lattice structure shared similarly along and between the central and second end portions. In addition, claim 83 now requires that this uniquely latticed segment along the first end

portion include M end-crowns that are less than N end-crowns along the opposite second end portion.

In addition to these amendments, Applicants have also further amended claim 83 with the still further clarifying language and/or further limitations of:

(a) the central portion is now clarified to include a mid-point along the longitudinal length between opposite ends of the stent, thus clarifying the originally intended meaning of the term "central" despite Applicants' belief this comports with the ordinary and plain meaning of the original language prior to this amendment; and

(b) requiring that the first latticed segment of the first end portion has fewer end crowns than the central and second end portion segments along the stent; and

(c) requiring that the amplitude of undulating pattern along the first end portion be greater than the amplitude of segments along the central and second end portions; and

(d) requiring that the first inter-crown distance along the first latticed segment of the first end portion be greater than a second inter-crown distance along at least second and third segment of the second end portion and central portion, respectively.

Applicant notes that the cited reference Von Oepen does not anticipate or suggest this combination as Applicants now require in amended claim 83. Applicant's claim 83 requires that a segment at one end of the stent have fewer crowns, greater amplitude, and greater inter-crown distance than other segments at the central and opposite second end portions. In contrast, the portion of Von Oepen recited in the Office Action under this rejection discloses a stent with quite an opposite structure: a first end that has more crowns, smaller amplitude, and smaller inter-crown distance than other segments along its central body and second opposite end portion.

These differences that Applicants' claimed structure present are several, including as Applicants have further amended Claim 83 to recite benefits in enabling improved overlapping stenting as Applicants' specification is replete with support and description.

Applicants further note that the amendments made to claims 88, 89, and 92 further distinguish over Von Oepen by specifying that the number of crowns in the first latticed segment is about half of that in the central and second opposite end segments, that the amplitude at the first latticed segment at the first end is about twice the amplitude of the central and second end portion segments, and the inter-crown distance along the first latticed segment of the first end is about twice that of the central body and second opposite end segments. Support for the present amendments, including these more specific limitations, is found in the present Application, in addition to other places, at: page 47, lines 1-12; page 48, lines 11-28; FIGS. 30A and 32A; and FIGS. 41, 42, and 45 (and supporting text). This resulting structure as claimed once again provides a particular benefit for example in overlapping with a similarly constructed stent in opposite orientation, where the results that might otherwise be doubled in overlapping section (e.g. re: metal mass or drug delivery) vs. the other stent regions are thus instead kept more uniform along the entire overlapped configuration as compared with other non-overlapped portions of the stents.

According to the amendment herein made to Claim 83, and other claims that depend therefrom, and accompanying remarks, Applicants respectfully request reconsideration and withdrawal of this ground for rejection as to Claim 83 and all claims that depend therefrom and otherwise subject to this ground for rejection.

b. Claims 94, 95 and 97 are rejected under 35 USC §102(b) as being allegedly anticipated by Vardi et al. (US 2002/0042650) ("Vardi").

Applicants have amended independent claim 94, which now requires that the first and second stents be similar to each other, but mounted in opposite longitudinal orientations relative to each other on separate delivery systems in order to provide for a certain overlapping configuration over a common guidewire and as also further developed in the claim as amended hereunder. In addition to other aspects of amendments made to claim 94 in order to provide further clarity to the language of the claim, Applicants have also clarified that the unique first lattice structure claimed for the first end of the respective stents differs from the lattice structure of segments along the

second opposite end and also the central portion that includes the mid-point of the length of each respective stent.

In contrast, the portion of Vardi recited in the recent Office Action in forming the basis of rejecting claim 83 included two stents "12" and "15" which are not of similar structure and which are not configured to be coupled in an overlapping configuration to form a tubular structure (e.g. "end-to-end") as Applicants' amended claim 94 currently requires. In stark contrast to Applicants' claimed overlapping stent system configured to overlap stents end-to-end, Vardi discloses a bifurcated stent system with one main lumen stent that includes a side port along the body portion between ends and through which the second branch lumen stent extends in branching fashion. This is a bifurcated stent, of which many have been disclosed and addresses a particular problem different from that addressed by Applicants' present claim 94. Applicants are not heretofore aware of any stent system previously disclosed prior to Applicants' present application for improved end-to-end overlapping stents, certainly not of the type Applicants have required in amended claim 94, and certainly not found in the presently cited art under this ground for rejection.

Further differences exist between Applicants' claims under this ground for rejection and the cited Vardi reference. In one such example, the Office Action assigned to "stent 12" of Vardi first and second portions, and a central portion therebetween. The "central portion" assigned to this Vardi stent in the Office Action conveniently was located toward one end of the stent and did not include the longitudinal center of the stent at all. This was done in order to then instead assign structures at the actual longitudinal center of the Vardi stent inappropriately to be part of a "first portion" that was then correlated to Applicants' "first end portion." This interpretation of Vardi is contrary to the ordinary and plain meaning of the term "central" in Applicants' claim, and was clearly a manifestation of impermissible hindsight analysis of Vardi in view of Applicants' own disclosure.

Notwithstanding this misinterpretation Applicants argue exists in the interpretation and application of Vardi under the Office Action, Applicants have nonetheless amended claim 94 to further clarify that by "central" Applicants require it to

include the longitudinal center of the stent. By this requirement, which Applicants assert existed both before and certainly after this amendment, it further follows that the Vardi disclosure does not anticipate or suggest this claim 94 – the Vardi "stent 12" does not anticipate or suggest Applicants' claimed combination of two similarly structured stents with both having a unique latticed segment at one end portion versus the opposite end and central portions.

It further follows that the grounds for rejecting dependent claims 95 and 97 are not proper, as for example with respect to dependent claim 97 Vardi does not in fact disclose or suggest overlapping confronting end portions between two stents, much less in order to form a tubular structure running along the resulting overlapped configuration. Vardi in contrast provides two stents that couple one end of one stent to a central portion of a second stent to produce a bifurcated branching structure in result. And, the structures of these two stents differ significantly from each other.

Accordingly, in view of the amendment made hereunder to independent claim 94, and accompanying remarks also presented hereunder, Applicants respectfully request reconsideration and withdrawal of this ground for rejecting claim 94 and all claims that depend therefrom.

c. Claim 105 is rejected under 35 USC §102(b) as being allegedly anticipated by Limon (US 6,273,910).

Claim 105 has been amended merely for clarity of language provided in the claim, whereas general scope of the claim is not believed to be significantly affected. Claim 105, both prior to and after this present amendment, specifically requires that the stent in a radially collapsed condition and delivery configuration with collapsed diameter is characterized as being plastically deformed from an initial diameter that is closer to an expanded diameter for the stent. This relationship represents a structural characteristic of the stent as collapsed, and such a stent differs structurally from another stent that is plastically deformed into the collapsed diameter from an initial diameter that is closer to the same collapsed diameter than the same expanded diameter.

In contrast, the portion of the Limon reference cited in the Office Action in allegedly providing support for this ground for rejection says nothing of such structural characteristics of its respectively disclosed stent, much less any relationship between varied diameters in context of initial diameter among them from which the stent is originally plastically deformed. Rather, the recited portion of Limon says merely the following:

> "In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent is first mounted onto inflatable balloon 40 on the distal extremity of the delivery catheter 38. The stent may be "crimped" down onto the balloon to ensure a low profile. The catheter-stent assembly can be introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). Guidewire 48 is disposed across the damaged arterial section with the detached or dissected lining 44 and then the catheter-stent assembly is advanced directly under the detached lining. The balloon of the catheter is expanded in a known manner, expanding the stent against the artery, which is illustrated in FIG. 2. While not shown in the drawing, the artery is preferably expanded slightly by the expansion of the stent to help embed the stent in the arterial wall to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate blood flow." (Limon, Col. 8 line 54- Col. 9 line 5)

This cited text thus merely describes crimping and subsequent expansion of a stent. Applicants' claim 105 particularly requires something much more specific than that, and requires a stent be plastically deformed in the crimped or collapsed configuration from an initial diameter that is closer to the expanded diameter than the crimped diameter. Limon does not disclose or suggest anything about what initial diameter the stent was crimped from. It is Applicants' understanding and belief that this is conventionally done in the art from an initial diameter closer to the crimped diameter than to the expanded diameter. However, Applicants have appreciated certain particular benefits of instead "working" the plastic deformation of the material that comprises a stent from an initial diameter that is larger and uniquely closer to the expanded outer diameter. In one exemplary benefit, as Applicants stated in the present Application as originally filed:

> "It should be noted that a further aspect of the present invention provides structures that may not be generally manufactured using standard stent manufacturing techniques, wherein stents are generally cut from tubes or rings at sizes that closely approximate the desired collapsed configuration for the stent. Instead, according to these embodiments that require overlapping end-crowns in the collapsed configuration, the stents are generally cut for example from a tube sized very close if not equal to the expanded diameter for the stent as shown in the Figure. Thereafter, the stent would be crimped down to the collapsed configuration wherein the enlarged end crowns are overlapped. Subsequent balloon expansion merely returns the stent to the size at which it was first formed." (Applicant's Specification, Pg. 46, lines 1-12)

Accordingly, at least one benefit is provided by a stent that is formed at an initial diameter much larger than its ultimately crimped diameter, and which benefit is not possible via a stent cut at an initial diameter closer to the crimped or collapsed diameter. Applicants claim this structural characteristic, while the cited art is not only deficient in any anticipation or suggestion of this, but rather is silent on the matter.

Accordingly, Applicants respectfully request that this ground for rejecting claim 105 please be reconsidered and withdrawn.

3. 35 U.S.C. §103 Rejections

a. Claim 93 is rejected under 35 USC §103(a) as being allegedly unpatentable over Von Oepen (US 6,017,365) in view of Vallana et al. (US 2003/0028242) ("Vallana").

Claim 93 has been amended to now associate the various ends of the stent in a manner that requires that the first end portion carrying a unique first lattice structure relative to the opposite second end and central portions provides a less dense therapeutic dose of bioactive agent than those other portions. The combination of benefits provided by this claimed combination of elements, including those elements incorporated into this claim by antecedent reference via dependency from independent claim 83, includes for example the ability to provide a system allowing such a stent to be overlapped with a second stent at this first end portion. Reducing the drug dose density at this end portion relative to the other stent portions allows for the drug dose density at the overlap region to be reduced vs. what could be as much as doubling a drug dose

density at area of overlap between two drug eluting stents without such beneficial modification. This is illustrated for example in the present Application at FIGS. 44 and 45 (and accompanying text, such as at page 55, lines 1 to 25).

The present ground for rejection recites a combination of Von Oepen and Vallana in alleging support for rejecting the instant claim. However, according to the amendments made to each of claims 83 and 93, this combination does not arrive at or otherwise render obvious the presently pending subject matter required by amended claim 93. Neither Von Oepen, nor Vallana, nor their combination, describes or suggests as obvious providing a stent with one end that delivers a lower density dose of therapeutic agent than the opposite end or central body portions of the stent – as Applicants now require in amended claim 93. Moreover, neither of these references, nor their combination, describes or suggests the need or perceived benefit to provide such result, for example to provide an improved drug eluting stent for overlapping use with another stent.

According to the amendment made to claim 93 and accompanying remarks, and incorporation into that claim of the combination of elements provided by independent claim 83 from which this claim 93 depends (and which Applicant argues should be considered patentable), Applicants therefore respectfully request reconsideration and withdrawal of this present ground for rejection.

b. Claims 96 and 98 are rejected under 35 USC §103(a) as being allegedly unpatentable over Vardi et al. (US 2002/0042650) in view of Davidson et al. (US 7,220,275).

Applicants have amended independent claim 94 herein, from which these claims depend, and have provided accompanying remarks to establish patentability of that independent claim in view of the present rejection held against that claim. According to this alone, Applicants further request that claims 96 and 98, which depend therefrom, also be held patentable.

In addition, Applicants assert the following also with respect to these dependent claims.

With respect to claim 96, the Office Action states initially that Vardi "disclose the claimed invention except for a bioactive agent…": This is not the case with respect to the combination of elements inherited into claim 96 by incorporation of antecedent independent claim 94 (as presently amended). In addition, however, the Office Action goes on to say that: "Davidson discloses having high concentration of a anti-restenosis agent at the open ends of the stents (second portions of the main and branch stents) and lower concentration at the bifurcated section (first portion)."

Claim 96 requires that the first "end" portion have lower elution profile than the elution profiles along the opposite second end or central portions. As inherent in the ordinary and plain meaning of "central", and as further clarified by Applicants' present amendment of independent claim 94, the presently claimed "central portion" includes the longitudinal "center" of the stent. Davidson teaches directly away, in the opposite direction, of the subject matter required by claim 96. It directs increased elution at both stent ends. Applicants direct reduced elution at one of the stent ends.

With respect to claim 98, the Office Action again alleges that Davidson teaches reduced elution at a first end portion of a stent by imappropriately capturing a more centrally located body portion of the stent into one of what the Office Action calls an end, while inappropriately shifting what Applicants call a "central portion" toward one end of the stent. Applicants' claim 98 requires that: "bioactive agent is eluted with an elution profile at the overlap region that is substantially less than double an elution profile along the respective second and central portions of the first and second stents." The Office Action admits that Davidson "does not disclose that the concentration at the overlap being less than double the concentration at the other portions." However, it goes on to say arriving at this would have been "within the routine skill of one of ordinary skill in the art to determine through routine experimentation and based on the teachings of Davidson, that the appropriate amount of drug concentration at the overlap should be substantially less than double the other portions…"

Davidson does not provide such teaching to give one of ordinary skill this direction, it teaches away from this result that Applicants claim – it directs increased drug elution at the ends of its stent. Moreover, neither cited reference, nor their

combination, provide or suggest this need or result as recognized or presented by Applicants' claim 98, and are not properly applied as references for end-to-end stenting in this present rejection. These cited references are both bifurcated stent disclosures for stenting branch lumens, whereas Applicants' claim 98 relates to a stent providing significantly different benefits in "end-to-end" overlapping for a resulting tubular structure (not a bifurcated, branched structure) extending along an overall stented length within a lumen (not branching lumens).

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejecting claims 96 and 98.

c. Claims 99-104 are rejected under 35 USC §103(a) as being allegedly unpatentable over Limon (US 6,273,910) in view of Vallana et al. (US 2004/0028242).

Applicants have amended independent claim 99 to now clarify more specifically that: "the first elution profile is greater than the third elution profile thereby the stent exhibits a gradient of elution profile with respect to the bioactive agent between the two opposite ends of the stent." Neither of these cited references, nor their combination, anticipate or suggest this relationship of drug elution along a stent. In fact, the recited portion of Vallana relied upon in the Office Action treats the ends of the stent uniformly in stating: "…the ends of the stent can receive anti-inflammatory agents since the end parts of the stent are the ones most exposed to the possible onset of inflammatory phenomena."

Applicants have appreciated in the invention required in claim 99 that significant benefit may be provided in a drug elution gradient between the two opposite ends of a stent – which is neither appreciated nor disclosed or suggested by either of these references. As Applicants have disclosed for example in the present Application, among at other places, at page 42 line 28 to page 43 line 9, the particular benefit of providing higher drug dose at the proximal or upstream end of a stent vs. at the downstream end. This benefit is not recognized or addressed, nor is a solution offered or suggested, by either or both of these cited references.

According to the clarifying amendment made herein to claim 99, and accompanying remarks, Applicants respectfully request reconsideration and withdrawal of this ground for rejecting claim 99, and all other claims under this ground of rejection that depend therefrom.

4. Conclusion

Applicants assert that the present amendments presented hereunder have been made with full support therefore in the present Application as originally filed. No new matter has been presented hereunder, nor is it believed that a new search should be required in view of these amendments.

All amendments made hereunder to the presently pending claims have been made in good faith in order to expedite the present application toward hopeful allowance, and have been made without estoppel, forfeiture, or dedication to the public with respect to the subject matter of the claims as pending prior to this amendment; Applicants reserve the right to pursue such claimed subject matter prior to this amendment in the future, such as for example through continuation practice.

Applicants believe in good faith that each and every ground for rejection has been adequately addressed and traversed in view of the present amendments and accompanying remarks, and respectfully requests that all present grounds for rejection be reconsidered and withdrawn and that a timely Notice of Allowance be issued in this case.

In the event that the Examiner determines that any open matter(s) or informality(s) remain which need be addressed prior to issuing a Notice of Allowance, Applicants respectfully request that the undersigned please be contacted at the phone number provided herewith and granted an interview in attempt to resolve any such matter(s) expeditiously prior to issuing a further formal written action adverse to such Allowance.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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